I have reviewed the "ECOFRAM Aquatic Report". Since my expertise is more directed towards effects than exposure, I have not commented on chapter 3 (exposure issues). Overall, I thought the ECOFRAM group did a good job pulling together much useful information on the application of ecological risk assessment to the Office of Pesticide Program's needs. In particular, I liked the recommendations to include some chronic testing in Tier 1, population modeling in Tier 2, and the use of joint probability curves to express results. General responses to the charge questions are provided below, followed by more specific comments.

1.   Is the draft report scientifically sound?

        Overall, the report is scientifically sound, but there are a number of specific areas where it could be strengthened. Some suggestions are provided in the answer to questions 3 and 4.

2.   Did the ECOFRAM work group address the charge? (Elements of the charge are noted below.)

        a.   Develop/validate tools at increasing levels of biological organization; consider direct and indirect effects.

        The work group did address tools at different levels of organization, up to the ecosystem level. Population-level effects are included in Tier 2, and ecosystem-level effects (microcosms) are considered in Tier 4. I did not find a discussion of ecosystem models. Indirect effects are largely inferred based on single species effects or are evaluated through the use of in microcosms in Tier 4.

        b.   Consider individual and population effects on aquatic fish and invertebrates first; aquatic plants if resources permit

        This aspect was addressed.

        c.   Methods should be developed in the context of the FIFRA regulatory perspective and EPA's ecological risk assessment framework (U.S. EPA, 1992) and should consider uncertainty.

        It appears that the FIFRA regulatory perspective and EPA's 1992 framework were followed. However, the framework has been superceded by EPA's Guidelines for Ecological Risk Assessment, which were published in May, 1998. Some terminology used in the ECOFRAM report differs from the 1998 guidelines (e.g., "measurement endpoint", "weight of evidence"). There could have been greater emphasis on the selection and use of assessment endpoints and on some aspects of risk characterization.

d.   Tools should have reasonable scientific certainty and be capable of acceptable validation in a reasonable time frame; probabilistic methods should use existing data where possible

Most of the tools proposed are fairly well validated, or their validation status is discussed. Probabilistic tools such as the joint probability curves make use of existing data.

e.   Risk estimate methods should consider species sensitivity, environmental fate, and other variables. Translate residue estimates into exposure estimates and routes of exposure.

This was done.

f.   Define methods clearly enough to ensure consistent assessments. State rationale for scenario choices. Specify/explain assumptions and uncertainties for easy understanding of significance of risk estimates.

The premise especially for Tiers 3 and 4 is that methods must be tailored to the questions being asked. While methods are generally clearly defined, a tool box of techniques is offered. Thus, different assessments will use different tools depending on the specific issues for a particular pesticide. Most of the tools included are accompanied by a discussion of assumptions and uncertainties.

g.   Define needed development/validation efforts.

I think the greatest needs here concern validation not just of the individual methods but of their implementation in an overall approach. For example, it would be useful to conduct a retrospective validation of the LOCs and to evaluate the utility of joint probability curves for risk characterization.

3.   What are the limitations for predicting risk using the approach described in the draft report?
4.   Taking into account your answers to the three questions above, what areas of the report need to be strengthened?

Some areas that could benefit from more discussion are listed below. I recognize that some of these topics may go beyond the ECOFRAM charge.

• Evaluate whether the selected Levels of Concern (LOC's) are appropriate.
• Provide a list/discussion of assessment endpoints as a key starting point for the process.
• Consider using a exposure and species sensitivity curves rather than a quotient in Tier 1.
• Provide a table showing the major sources of uncertainty and their relative magnitude as a way of thinking about the usefulness of acquiring additional data.

- Discuss whether considerations of pesticide effects could be made more specific to the geographic areas of use.
- Provide more discussion of mixture toxicity issues, including interactions among pesticides likely to be used in the same area.
- Recommend validating the proposed approach by conducting a retrospective evaluation using existing data.
- Discuss the utility of ecosystem models as a supplemental tool for evaluating indirect and other effects.
- Discuss the application of lines (weight) of evidence approaches in risk characterization.
- Elaborate on how to consider the spatial scale of effects in risk characterization.

5.   At what point in the risk assessment process is the certainty level high enough to support the consideration of risk mitigation? What is the minimum level of technical information and scientific understanding that is necessary to evaluate whether risk mitigation would be necessary and/or effective?

The ECOFRAM ecological risk assessment approach uses the joint probability curves as a key risk estimation approach beginning with Tier 2. Thus, decisions concerning risk mitigation could be made at this point. The catch is that there must be a consensus on assessment endpoints (fish and invertebrate populations, percent of species affected, etc.) as well as the boundary for "acceptable" risk in the joint probability curve. Agreement on these policy calls may be difficult to achieve, but is essential. In addition, there must be understanding not only of the risks but also of the effectiveness and reliability of the proposed mitigation measures.

Additional comments on the ECOFRAM report are provided in the table below.

Page/Line	Comment
General Comments	1. How to address mixture toxicity issues (p. 2-53, 19-24)? 2. How could assessments be made more representative of the environments in which the pesticides will be applied? (See p. 2-50, 21-25; 2-51, 19-24; p. 2-53, 1-5 and 8-11) 3. Would be interesting to characterize the relative uncertainties associated with different parts of the exposure/effects evaluation (p. 4-3 ff, 12-15). 4. How often is a pesticide passed out of Tier 1 with no presumed effects or need for further evaluation? If it seldom happens, why not just begin with Tier 2? 5. A key issue is the willingness of risk managers to make decisions based upon the risk assessment results. Managers and assessors should work together to define assessment endpoints and risk thresholds and incorporate them into the risk assessment/characterization effort. 6. Weight of evidence considerations in risk characterization, e.g., field incident reports, etc. (p. 4-3, 6-10) - needs more discussion.

Page/Line	Comment
2-6, 6 ff	Need to define what the assessment endpoints are in this process; they are not clearly specified. Nor is there a clear statement of management goals and objectives. Should recommend generation of validation data to demonstrate that risk quotients are indeed protective, e.g., retrospective studies for pesticides where lab and field data are available.
2-7, 21	Use "concentration-response" or "stressor-response" instead of "dose-response".
2-9, 7-9	Much more work needs to be done to provide "clear generic guidance on the tier system".
2-13, 8-16	Prefer "measures of effect" to "measurement endpoint". Need to better define assessment endpoints - only a couple of examples are provided.
2-16, 8	Somewhere in the document, should define "ecological significance".
2-20, 4-6	Risk assessment proceeds beyond tier 1 only for taxa of potential concern. This may be too restrictive especially if indirect effects are considered important.
2-20, 20	All the LOCs deserve further discussion/justification. Regarding the 0.05 LOC, in a generic assessment, when could you assume that an endangered species is not present?
2-22, 7-11	If your exposure scenarios are watershed/region specific, why not a similar effort for effects evaluation?
2-30, 22; 2-37, 12; 2-38, 25	I could not find figures 2-2 and 2-3.
2-41, sec. 2.4.3	EPA' Science Policy Council is developing guidance for risk characterization. A draft handbook has been written and peer-reviewed. If possible, this effort should be mentioned here.
2-45, 7-10	Biological and social significance of species are important, but are not addressed here, and are difficult to address in a generic context.
2-50, 21-27; 2-51, 19-24; 2-53, 8-11; 2-53, 19-21	ECOFRAM itself should discuss making assessments more directed to specific geographic regions, multiple stressors, and assessment endpoints.
4-1 to 4-4	Need to consolidate uncertainty discussion - it's too fragmented. Areas of disagreement should be included as alternative views.

Page/Line	Comment
4-1, Section 4.1	Why not provide a table showing sources and relative degrees of uncertainty for both exposure and effects. For example, tier 2 effects focus on intra-specific variations in toxicity - how important is this relative to other uncertainty sources, such as between species and effects of time-varying exposures (2-24, 13-15)?
4-5, 33-34	Could a couple references be cited here?
4-8, 6-13	Some have questioned the generalization that functional parameters are less sensitive due to redundancies. For example, see Pratt, J.R. and J. Cairns Jr. 1996. Ecotoxicology and the redundancy problem: understanding effects on community structure and function. Pp. 347-370 in Ecotoxicology: a Hierarchical Treatment. M.C. Newman and C.H. Jagoe (eds). Lewis Publishers, Boca Raton
4-8, 15-18	I'm not sure it's appropriate to flatly state that protecting 90% of aquatic species is ecologically quite conservative. In any case, more attention needs to be paid to assessment endpoints and management goals. Do they involve populations of individual organisms (e.g., using population models), or community structure (protect a given percent of species in a community), or both?
4-8, 20-28	Recovery of populations. Paragraph addresses invertebrates but not longer-lived species. Some evidence that systems retain an historical record of disturbance and may in fact reflect changes due to even temporary disturbances (e.g., Landis, Moore). Could use more discussion of the recovery of ecological systems.
4-10, 11-13	What about other pesticides used in a watershed? How to address?
4-11, 25-26	Several aquatic species, including fish such as medaka and rainbow trout, have been used in carcinogenicity tests. But it is probably not an important issue for ECOFRAM.
4-14, 36	ELS tests - note that issues have been raised regarding the predictive capability of these tests, notably for their inability to predict chronic effects associated with pulp and paper mill effluents.
4-18, Table 4-1	It is surprising that the work group did not discuss question the LOC values. While establishing the exact value may be responsibility of the risk managers, some justification should be provided for these numbers. For example, there should be empirical data suggesting an appropriate degree of protection; otherwise, the numbers appear to be totally arbitrary. 4-18; 21-24. Despite the assertion, I would be uncomfortable citing minimal concern for a widely-used pesticide based solely on Phase I screening, even if it is conservative.
4-19, 3-6	If tier 2 effects are simply additional analysis of tier 1 data, why not to apply at least some of the analyses in tier 1?

Page/Line	Comment
4-21, 21-25	Will there ever be a circumstance when evaluating time-varying or repeated exposures is inappropriate?
4-26, 34-35	Isn't substantial variability among taxa to be expected? How much is substantial?
4-29 to 4-44	The TTE discussion is good, but could be cut down somewhat; it's too detailed relative to other sections.
4-46	While I agree that reporting population-level risks is a good idea, there are still some difficult issues: what is the appropriate population endpoint, what species should be selected for modeling, etc.?
4-47, 5-7	Could use more guidance on how to apply and use population models in regulation. There is no specific spatial-temporal context to be evaluated (4-46, 27-28). Which populations are important for situations where pesticide risks are considered for generic ecosystems? Good review of models but they could be more effectively presented if their specific utility to the pesticide situation could be developed further. Need to develop more on the type of information provided on 4-62, 1-9.
4-68, 12-13	Need to resolve questions.
4-85, 32-36	This brief example is not very useful by itself.
4-89 to 4-90, section 4.6.5	This section has redundant material and needs editing.
4-108, 19-25, 26-28	Need to resolve this issue concerning the use of equilibrium partitioning data.
4-109, 35 to 4-110, 2	Focus is on measurement endpoints, but the assessment endpoints have not been identified.
4-111, 1-12	Proposed set of sediment assays may be unrealistically large.
4-112, 24-25	The number of data points required for distributional analysis is discussed in section 4.5.1.1 (p 4-65) and should be referenced here.
4-15, 5; 4-112 ff	Agree with use of regression analysis for chronic tests vs. NOEC/LOEC. But there is no discussion of a choice of x in the EC_x. (At one point an EC_{10} is proposed).

Page/Line	Comment
4-121	Please define "ecologically significant" and "ecologically acceptable".
4-123, 23-27	The recommendation is not to use fish in microcosms; but, in fact, fish endpoints may be most important to managers (4-119, 6-8). Presuming a lack of indirect effects (or other effects) based on single species test results may not be a good idea (19-34).
4-126, 12 ff	Recovery - need to consider the point of view of Landis et al. and Matthews et al. (1996).
4-130, 4-11	EPA's ecorisk guidelines include the following comments on ecologically adverse effects: "Adverse ecological effects, in this context, represent changes that are undesirable because they alter valued structural or functional attributes of the ecological entities under consideration. The risk assessor evaluates the degree of adversity, which is often a difficult task and is frequently based on the risk assessor's professional judgment. ... The following are criteria for evaluating adverse changes in assessment endpoints: • Nature of effects and intensity of effects • Spatial and temporal scale • Potential for recovery." The ECOFRAM report should recommend consideration of spatial scale in characterizing the risks of pesticides. The extent of pesticide use and application in areas adjoining critical ecological habitats are important aspects of ecological adversity. Because ecological adversity and significance incorporate both scientific and value judgements, they should be based on selection of assessment endpoints that incorporate both scientific and management concerns.
4-134	Recommendations should be grouped by topic to facilitate presentation.